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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,063	MARLOWE ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 8/29/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant's cancellation of claims 1-13 and 23-25 in the response filed 8/29/2006 is acknowledged.

Claims 14-22 are the current claims hereby under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bluestein et al. (US P/N 4,780,423) in view of Lucas (US P/N 6,996,538).

The claimed invention is directed to a method for preparing a binding-ready biological sample to be used in a said binding assay and an automated inventory checking system. The method involves receiving a design for a binding assay, preparing an experiment design and choosing a robot method for generating said binding-ready biological sample, generating work instructions, and executing said work instructions on robot stations to generate the binding-ready biological sample. The

method also involves an automation method for checking supplies and materials required for experiment design and ascertaining whether there are enough materials in inventory.

Bluestein et al. teaches the first step of claim 14 at col. 6, lines 35-48. Bluestein et al. discusses receiving an IMMOPHASE radioimmunoassay kit for performing an assay as required in the first step, which cites receiving a binding assay design.

Bluestein et al. teaches the second step of claim 14 at col. 8, lines 10-31. Bluestein et al. explicitly discusses changes made in the radioimmunoassay kit used in Example 1 as preparative steps for designing an experiment for generating a binding-ready biological sample.

Bluestein et al. teaches the third step of claim 14 at col. 8, lines 61-69 and col. 9, lines 1-30. Bluestein et al. discusses the use of the Screen Machine System manufactured by Pandex Laboratories as the choice of a robot method for generating a binding ready biological sample and executing work instructions on robot stations to generate the binding ready biological sample. At col. 9, lines 8-12, Bluestein et al. discusses a microprocessor that can be programmed for generating work instructions for generating biological sample, such as adding wash solutions and reagents. At col. 9, lines 13-15, Bluestein et al. discusses the execution of work instructions for generating the biological sample using the SCREEN MACHINE.

Bluestein et al. teaches optimizing materials usage and plate layout for generating biological sample at Col. 8, lines 15-26 and lines 53-57, where changes were made for creating high precisional capabilities and a comparison shows that the

assay of this invention is capable of achieving more rapid test results, which is a result of optimizing materials usage and plate layout.

Bluestein et al. teaches claims 20 and 22 at col. 4, lines 62-69 and col. 5, lines 1-4. Bluestein discusses the biological sample as being a receptor tissue protein. Bluestein also discusses the assay as comprising a ligand and a specific binding partner to the ligand, which is a type of hybridization assay.

Bluestein et al. teaches part of claim 20 at col. 4, lines 62-69 and col. 5, lines 1-4. Bluestein discusses the biological sample as being a receptor tissue protein. If the sample in the assay is a receptor tissue protein, then it necessitates an extraction in order to isolate the protein from the tissue for use in the assay. Bluestein does not teach updating inventory after extracting a constituent sample. Additionally, Bluestein et al. does not teach an automation method for checking supplies and ascertaining whether there are enough materials in inventory, sending a request, and notifying an operator if there are not enough materials in inventory.

Lucas teaches claim 16, checking inventory for required materials, at col. 2, Lines 45-53. Lucas discusses an inventory management system, which automatically checks supplies and materials required as needed.

Lucas teaches claim 17, at col. 8, lines 65-67 and col. 9, lines 1-10. Lucas discusses sending an inventory request, receiving a list of materials and ascertaining whether there are enough materials.

Lucas teaches claim 18, at col. 9, lines 63-67 and col. 10, lines 1-53. Lucas discusses sending an inventory request containing a list of materials as a customer

selecting search criteria which queries a list of products and product descriptions that match the inventory request and returns the information.

Lucas teaches claim 19, at col. 10, lines 33-68 and col. 11, lines 1-46. Lucas discusses sending inventory requests when not enough materials may be available and notifying an operator or sales consultant and continue scanning orders until requests are fulfilled.

Lucas teaches part of claim 20 at col. 9, lines 50-55. Lucas discusses updating customer inventory.

It would be obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bluestein et al. with Lucas because the automating inventory checking system of Lucas will enhance the automation of the automation system of generating a binding assay.

Response to Arguments

Applicant's arguments filed 8/29/2006 have been fully considered but they are not persuasive.

Applicants argue that Bluestein's experiments in examples 1 and 2 pertaining to a radioimmunoassay and fluorescent assay were manually performed and that the automated fluourescence immunoassay performed in example 3 using the Pandex Screen Machine, does not teach that the preparation of the binding-ready biological samples that are supplied to the Pandex Screen Machine is automated.

This argument is not persuasive because Bluestein, at col. 9, lines 1-12, does disclose the automation of performing the particle concentration fluorescence

immunoassay and specifically states at col. 9, lines 12-15, that this same automated Screen Machine was used to perform the 2 site immunometric assay for ferritin described in Examples 1 and 2. Examples 1, 2, and 3 all have automated preparations and these examples describe the automated assay experiments being performed and specifically disclose the preparation of adding the controlled pore glass (CPG) antibody and adding the fluorescein labeled anti-ferritin antibody to each tube, which represents "a robot method for generating said binding-ready biological sample" because of the automated processes. As stated in the previous office action, receiving or obtaining the radioimmunoassay kit represents receiving a binding assay design for a binding assay.

Applicants further argue that Bluestein's use of a Pandex Screen Machine does not disclose the preparation of a binding-ready biological sample, implemented through the choosing, generating, and executing steps of the claims. Additionally, applicants allege that the screen machine is programmed to automatically perform a fluorescence immunoassay on a pre-prepared sample and is not enabled to prepare a binding-ready biological sample.

As stated above, it is clear that the Pandex Screen Machine is fully capable of preparing a binding-ready biological sample, as disclosed in examples 1, 2, and 3. The automated deposit of the CPG antibody to each tube followed by the deposit of the fluorescein labeled anti-ferritin antibody to each tube demonstrates the preparation of a binding-ready biological sample. The automated deposit of the CPG antibody to each tube is a demonstration of the preparation of a binding-ready biological sample, which is followed up by the binding of the labeled anti-ferritin antibody, which is also an

automated deposit. Therefore, it is clear that the Pandex Screen Machine is fully capable of preparing a binding-ready biological sample. With respect to a binding-ready biological sample implemented through the choosing, generating, and executing steps as cited in the claims, Bluestein specifically states at col. 9, lines 8-12, that the Screen Machine utilizes a microprocessor that can be ***programmed*** to add reagents, which represents the preparation and generation of work instructions for the robot, and wash solutions any number of times in any desired sequence, which represents the execution step as well. Therefore, the microprocessor is programmed according to the experiment design, which in this case the design was based on the reception of the radioimmunoassay kit, and the program generates the automated instructions for the robot to execute the preparation of the binding-ready biological sample.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

27 November 2006

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER